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|--|-------------|-----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/376,604 | 08/18/1999 | RAGUPATHY MADIYALAKAN | AREX-P03-004 | 6693 |
| 7590 | 06/07/2004 | | EXAMINER | |
| Matthew P Vincent Ropes & Gray One International Place Boston, MA 02110 | | | NICKOL, GARY B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------|------------------------|---------------------|
| Advisory Action | Application No. | Applicant(s) |
| | 09/376,604 | MADIYALAKAN ET AL. |
| | Examiner | Art Unit |
| | Gary B. Nickol Ph.D. | 1642 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 3 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. Applicant's reply has overcome the following rejection(s): 112 1st paragraph (Budapest Statement rejection only).
4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 113, 117-120, 123, 125, 129-135, 137-139, 141-144, 170-175, 180-182, 185, 187, 190-204, 206-209, and 235-242, 245-246, 251-257.

Claim(s) withdrawn from consideration: 243,244 and 247-250.

8. The drawing correction filed on _____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. Other: _____

**GARY NICKOL
PRIMARY EXAMINER**

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit: 1642

Continuation of 2. NOTE: The suggested amendments will not be entered because they appear to change the scope of the previously examined subject matter which would require new parameters for consideration.

Continuation of 5. does NOT place the application in condition for allowance because: the rejections under 35 USC 102(e) and 103(a) are maintained. Applicants have argued that the prior art does not contemplate a therapeutic host humoral and or T cell response. In particular applicants note that the decrease in tumor volume in the '159 patent began immediately after (day 8) the administration of anti-OFP (day 7). Applicants attest that both humoral and cellular immune responses take more than one day. This argument has been considered but is not found persuasive. The abstract of the prior art is clearly directed to mechanisms involving the immune response via "anti cancer immunotherapy"; which in applicant's own words (After-final response, page 12) includes humoral responses and cellular immune responses. Further, the premature anti-cancer response see in Figure 1 may be attributed to the pre-mature mice used in the experiment which have an impaired immune system. This, however, does not rule out that cellular and humoral immune responses did not contribute in the following days post administration-- note that the prior art teaches that these mice still have high "natural killer cell activity" and that measured anti-cancer responses were observed on multiple occasions (see Table 1) six days after treatment. Further, the rejection under 112 1st paragraph (new matter) is maintained. Recitation of a murine monoclonal antibody does not adequately describe the scope of the claimed subject matter drawn to all "non-human" monoclonal antibodies. GN